IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8928

Bartle, J. August 22, 2012

Evelyn N. Philbeck ("Ms. Philbeck" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[3] See Settlement Agreement §§ IV.B.1.a. & I.22.

In October, 2009, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R.

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2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

Boxberger, M.D. Based on an echocardiogram dated September 8, 2008,[4] Dr. Boxberger attested in Part II of Ms. Philbeck's Green Form that she suffered from severe mitral regurgitation, mitral valve prolapse, and chordae tendinae rupture.[5] In addition, Dr. Boxberger attested that claimant had surgery to repair or replace the aortic and/or mitral valve(s) following use of Pondimin® and/or Redux™.[6] Based on such findings, claimant would be entitled to Matrix B-1, Level III benefits in the amount of $131,589.[7]

In the reports of claimant's March 7, 2002 and December 18, 2002 echocardiograms, the reviewing cardiologist, C. K. Lai, M.D., F.A.C.C., indicated that claimant had mild

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4. Because claimant's September 8, 2008 echocardiogram was performed after the end of the Screen Period, claimant relied on echocardiograms dated March 7, 2002 and December 18, 2002 to establish her eligibility to Matrix Benefits.

5. The presence of either mitral valve prolapse or chordae tendinae rupture requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See Settlement Agreement §§ IV.B.2.d.(2)(c)ii)b) & IV.B.2.d.(2)(c)ii)c).

6. Dr. Boxberger also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class IV symptoms. These conditions are not at issue in this claim.

7. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Philbeck has met these requirements, the only issue is whether she is eligible for benefits.

mitral regurgitation. Dr. Lai, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitation jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

In October, 2009, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for finding mild mitral regurgitation based on claimant's March 7, 2002 or December 18, 2002 echocardiograms. Specifically, Dr. Gillespie determined:

> Review of the apical views showed trace [mitral regurgitation] with Nyquist Limit set at appropriate level i.e. ≥ 50 cm/sec. At Nyquist Limit set at 40 cm/sec is the only time [mitral regurgitant] jet is seen in the mild range. The parasternal views showed no [mitral regurgitation]. Review of the study done on 3/7/02 showed trace [mitral regurgitation] also.

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination denying Ms. Philbeck's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8]

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8. Claims placed into audit on or before December 1, 2002 are (continued...)

In contest, claimant argued that both her March 7, 2002 and December 18, 2002 echocardiograms demonstrated mild mitral regurgitation. In support, Ms. Philbeck submitted an affidavit of Roger W. Evans, M.D., who concluded:

> Claimant's echocardiogram tape of 03/07/2002 shows "mild" mitral valve regurgitation with a RJA/LAA ratio of 10%. This is seen in the long axis views and in the 4-chamber view. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that this echocardiogram tape shows "mild" mitral valve regurgitation when answering Question C.3.a. in Part II of the Green Form.
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> ....
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> Claimant's echocardiogram tape of 12/18/2002 shows "mild" mitral valve regurgitation with a RJA/LAA ratio of 10%. The jet extends 2 cm from the valve orifice into the left atrium. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that this echocardiogram tape shows "mild" mitral valve regurgitation when answering Question C.3.a. in Part II of the Green Form.

The Trust then issued a final post-audit determination, again denying Ms. Philbeck's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

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8. (...continued)
governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Philbeck's claim.

show cause why Ms. Philbeck's claim should be paid. On April 9, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8456 (Apr. 9, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 17, 2010. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for finding that claimant's

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

March 7, 2002 and/or December 18, 2002 echocardiogram(s) demonstrated at least mild mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we conclude that there is a reasonable medical basis for this finding, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Philbeck raises the same arguments she made in contest. In addition, she asserts that inter-reader variability accounts for the difference in opinion between her cardiologists and the auditing cardiologist and Technical Advisor.

In response, the Trust argues that claimant did not establish a reasonable medical basis for finding mild mitral regurgitation on either the March 7, 2002 or December 18, 2002 echocardiogram as she simply asserts there is a reasonable medical basis because Dr. Evans agrees with Dr. Lai's findings. The Trust also asserts that Ms. Philbeck failed to submit any documentation rebutting Dr. Gillespie's determination that the December 18, 2002 echocardiogram only showed mild mitral regurgitation when the Nyquist limit was inappropriately set.

The Technical Advisor, Dr. Vigilante, reviewed claimant's March 7, 2002 and December 18, 2002 echocardiograms

and concluded that there was a reasonable medical basis for finding mild mitral regurgitation. In particular, Dr. Vigilante determined that:

> Visually, trace to mild mitral regurgitation was suggested in the apical views [of the March 7, 2002 echocardiogram] with a central jet. In the parasternal long-axis view, I was able to determine a thin jet of mitral regurgitation in one beat only. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet could be best evaluated in the mid portion of systole. I was able to accurately planimeter the mitral regurgitation jet in the mid portion of systole. In the apical four chamber view, the largest representative RJA was 1.5 cm2. The LAA in the apical four chamber view was 19.7 cm2. Therefore, the largest representative RJA/LAA ratio was less than 8% consistent with mild mitral regurgitation....
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> In the apical four chamber view [of the December 18, 2002 echocardiogram], the largest representative RJA in the mid portion of [systole] was 1.3 cm per second. The LAA in the apical four chamber view was 20.2 cm2. Therefore, the largest representative RJA/LAA ratio was 6% in the apical four chamber view consistent with mild mitral regurgitation.
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> In response to Question 1, there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. on the Green Form signed on August 10, 2002. That is, the echocardiogram of March 7, 2002 demonstrated mild mitral regurgitation with an RJA/LAA ratio of less than 8% in the apical four chamber view.
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> In response to Question 2, there is a reasonable medical basis for the Attesting Physician's answers to Green Form Question C.3.a. on the Green Forms signed on

> February 17, 2003 and January 3, 2003. That is, the echocardiogram of December 18, 2002 demonstrated mild mitral regurgitation with an RJA/LAA ratio of approximately 6%.

After reviewing the entire Show Cause Record, we find that claimant is eligible to receive Matrix Benefits based on damage to her mitral valve. The Settlement Agreement states that the following Class Members are eligible to receive Matrix Benefits:

> Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement further defines "FDA Positive" as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must establish at least mild mitral regurgitation to be eligible to seek Matrix Benefits for a claim based on her mitral valve.

In reviewing claimant's record, Dr. Evans and Dr. Vigilante reviewed the March 7, 2002 and December 18, 2002 echocardiograms and concluded that they both demonstrated mild mitral regurgitation. Specifically, Dr. Evans concluded that each echocardiogram demonstrated an RJA/LAA ratio of 10%, and Dr. Vigilante determined that the March 7, 2002 echocardiogram demonstrated an RJA/LAA ratio of less than 8% and the December 18, 2002 echocardiogram demonstrated an RJA/LAA ratio of

6%. With respect to the December 18, 2002 echocardiogram, Dr. Vigilante noted that he was able to determine the level of claimant's mitral regurgitation despite the Nyquist settings. Despite an opportunity to do so, the Trust does not refute or respond to Dr. Vigilante's conclusions. As noted previously, mild mitral regurgitation is present where the RJA/LAA ratio is more than five percent (5%) and less than twenty percent (20%). See Settlement Agreement § I.38.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will reverse the Trust's denial of Ms. Philbeck's claim for Matrix B-1, Level III benefits.